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EXAMINER

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ART UNIT PAPER NUMBER

3761

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Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of claims 1, 3-12, 14-18, 20-22, 24-27, 61-63, 65-72, 74-76, 92, 102-103 in Paper No. 10 is acknowledged. However, the election/alignment of the newly added claims is in error. Claim 71 depends upon claim 19, a non-elected claim, hence claim 71 is also non-elected. Claims 72 & 74 depend upon claim 28, also a non-elected claim, hence claims 72 & 74 are also non-elected.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10, 20, 69 & 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to the use of "and/or" in claim 10, it renders the claim scope indefinite because it is unclear if applicant intends one or the other or both to be the scope of the claim.

In regards to claim 20, the claim is dependent upon claim 19, which is now canceled, thus rendering the claim indefinite. The claim is presumed to depend upon claim 16 for examination purposes.

4. Claim 69 recites the limitation "the carrier gas " in line 1. There is insufficient antecedent basis for this limitation in the claim.

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5. Claim 102 recites the limitation "the passage" in line 5. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 102 recites the limitation "the trachea" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. Claim 63 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 62.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 61 & 102-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Koch (US 4465067).

In regards to claims 1, 3, 61 & 102-103, Koch discloses a method for delivering therapeutic gas to a person having a nasal/oral mucous membrane, said method comprising the generation of a flow of therapeutic gas (via conduit 8), infusion of the nasal or oral mucous

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membranes (note that by dint of anatomy alone of the oronasal cavity both cavities will be infused when gas is nasally delivered) with the flow of therapeutic gas (note the nasal interface) wherein the person refrains from inhaling (note that the gas is delivered to insufflate the oronasal cavity, hence delivery is not primarily for breathing but insufflation, if the user were to breathe the gas could not insufflate the nasal cavity). In regards to claims 61/102/103 this refrainment of breathing to facilitate insufflation would result in inhibition of the passage of the gas into a user's trachea & lungs.

In regards to claim 3, Koch discloses the use of oxygen.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch.

In regards to claim 6, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, Koch substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 7, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 8 & 9, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

12. Claims 5 & 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch as applied to claim 3 above, and further in view of Zapol (US 5485827).

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Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose use of a carrier gas. However, Zapol disclose such (col. 7 lines 25-35). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zapol and used them with the device of Koch. The suggestion/motivation for doing so would have been to minimize secondary reactants among the gases delivered to the user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 75, the suggested device discloses the use of nitric oxide as the therapeutic gas the carrier gas is non-oxidizing and they blend to form diluted nitric oxide gas (see Zapol col. 7 lines 20-25).

13. Claims 4, 62-63 & 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch in view of Fukunaga (US 5983891).

In regards to claim 4, Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose the therapeutic gas consisting essentially of Carbon Dioxide. However, Fukunaga disclose such (See Summary of Invention discussing capnia modes of gas deliver). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Fukunaga and used them with the device of Koch. The suggestion/motivation for doing so would have been to

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promote the oxygenation of the user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 62 & 63, Fukunaga discloses the carbon dioxide gas being in a carrier gas (the remaining components of the ventilatory gasses being delivered to the user).

In regards to claim 65, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 66, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 67 & 68, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

14. Claims 10-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch as applied to claims 1/102 above, and further in view of Zimmerman (US 4273124).

In regards to claim 10, Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose allowing the flow to exit another nostril and/or the mouth. However, Zimmerman disclose such (See the abstract last line, note figs 6-8 and supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zimmerman and used them with the device of Koch. The suggestion/motivation for doing so would have been to optimize

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the flow of gas and prevent the back pressure buildup in the oro-nasal/sinus cavity. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 11, the suggested device discloses that all gas goes through the "exhaust" nostril when the mouth is closed (See figs 5 & 6 and supporting text).

In regards to claim 12, the suggested device noted above substantially disclose the claimed invention except for the reversal or rearrangement of gas input through the mouth and out the nasal passage(s).

It is noted that applicant's specification does not set forth this reversal or rearrangement, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, the suggested device is fully capable of adjustment of the flow rate to the patient's perceived comfort level, the

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In regards to claim 15, decrease of flow rate resulting in increase of treatment time obvious to one of skill in the art because flow reduction means less therapeutic gas is being delivered to a patient and hence it will take more time to deliver the same dose to the patient to achieve the same therapeutic result.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (US 2860634).

In regards to claim 16, Duncan substantially discloses the instant application's claimed invention to include the release from a hand held dispenser (See Fig 2) a flow of treatment gas comprising oxygen, but does not explicitly disclose the specific flow range of 0.5 cc/sec to 20 cc/sec.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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In regards to claims 20, 69-70, Duncan substantially discloses the instant application's claimed invention to include the use of other gases, liquids or drugs than oxygen, but does not disclose the use of a carrier gas that is biologically active. However one of skill would view that in light of this teaching of Duncan and the state of the art that the use of a carrier gas that is inert/biologically active is obvious e.g. a composite gas that uses an inert carrier gas such as "air" which has the inert carrier gas of nitrogen but which is also a biologically active material.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 21, Duncan discloses the dispenser as being suitable for sealing against the user's nasal passages.

In regards to claim 22, Duncan discloses the dispenser that is fully capable of sealing against a user's mouth. Furthermore nasal and oral patient airway interfaces are known interchangeable mechanical equivalents in the art (see Fukunaga).

In regards to claim 24, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially discloses the claimed invention except for this flow rate range.

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It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 25 & 26, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 27, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

16. Claim 76 rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan as applied to claim 16 above, and further in view of Zapol (US 5485827).

Duncan substantially discloses the instant application's claimed invention, but does not explicitly disclose use of nitric oxide as the therapeutic gas, a carrier gas that is inert and non-oxidizing and which form a diluted mixture of nitric oxide. However, Zapol disclose such (col. 7 lines 25-35). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zapol and used them with the device of Duncan. The suggestion/motivation for doing so would have been because Duncan discloses the use of composite therapeutic gases (col. 3 lines 65-75) and Zapol discloses the use of a composite gas for therapeutic treatments (col. 7 lines 20-35). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Allowable Subject Matter

17. Claim 92 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not anticipate or suggest the method step of mixing reagents to produce carbon dioxide for capnia respiratory therapy.

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Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5908870, 5562644, 4934359

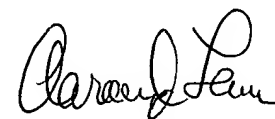
Yoga Cure for Headaches, YogaJournal.com Jan/Feb 1999; Yoga: A Cure for Headaches, May 2001; Yoga Rx for Headaches, Yogabasics.com 2001; Can't stop the Pain 13 Jun 2001, Abcnews.com; Oxygen Therapy for Headaches www.headaches.com 2002; Smoking Cessation: New strategies and opportunities for pharmacists. American Druggist, Jan 1997; Intranasal fenoterol in asthmatic subjects: An alternative route of administration, J. Of Clinical Immunology Oct 1984; Zysk: The Science of Respiration and the doctrine of the bodily winds in ancient India, J. Of American Oriental Society 113.2 (1993).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



JF Weiss

December 8, 2002



Aaron J. Lewis
Primary Examiner